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RIVER CITY
ORTHOPAEDIC
SURGEONS,
P.S.C.

- *Adult* Spinal Surgery
- *Arthroscopic* Surgery
- Foot and Hand Surgery
- *General Orthopaedics*
- Sports *Medicine*
- Total *Joint Replacement*

1999 DEC 13 P3:14

December 6, 1999

Document Management Branch (HAFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket #97N-484S

Dear Sirs:

I send you this letter 'to' be placed into your records and for documentation purposes. As you are aware this particular docket refers to consideration to place allograft bone bank materials under regulatory control as medical devices.

I strongly urge you not to approve this proposal. Allograft bone bank bone are not medical devices. They are not manufactured by humans. These are sterilized, cleansed body tissues and it would be absolutely impossible and inconceivable for bone banks to be charged with sterilizing, processing, and storing this material to satisfy any FDA pre-market requirements, including clinical trials and the submission of regulatory documents as if these companies were manufacturing artificial metallic or plastic components to be inserted into the human body. It has been well-documented throughout years and years of medical research that the reinsertion of'human bone into other humans is safe and efficacious as an adjunct to the treatment of bone disease and injuries.

The FDA already regulates bone preparation and storage issues. It is absurd for the FDA to now manufacture a regulatory process which has no legitimacy and would simply deny patients access to something that has been proved over many years to be judicious, appropriate and efficacious.

97N-4845

C103

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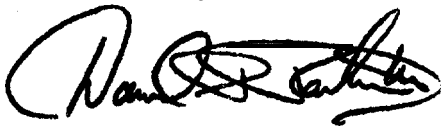
I strongly urge you to not accept the consideration of this regulation.

Yours truly,



David P. Rouben, M.D.

DPR/ks/MBS
(Dictated not read)
DPRLTR12.06

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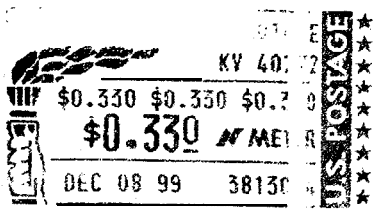

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